PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 26 January 2001 (26.01.01)	
International application No. PCT/US00/11389	**Applicant's or agent's file reference** 7518
International filing date (day/month/year) 28 April 2000 (28.04.00)	**Priority date** (day/month/year) 29 April 1999 (29.04.99)
Applicant CAUSEVIC, Elvir et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

29 November 2000 (29.11.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was [ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland** Facsimile No.: (41-22) 740.14.35	Authorized officer R. Forax Telephone No.: (41-22) 338.83.38

14

PATENT COOPERATION TREATY

PCT

REC'D 27 AUG 2001

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 7518	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/11389	International filing date *(day/month/year)* 28 APRIL 2000	Priority date *(day/month/year)* 29 APRIL 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/00 and US Cl.: 600/559		
Applicant CAUSEVIC, ELVIR		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 NOVEMBER 2000	05 JULY 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRIAN SZMAL Telephone No. (703) 308-0858

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/11389

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-15 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of ____

[X] the claims:
pages 16-20 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of ____

[X] the drawings:
pages 1-5 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of ____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of ____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language ____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE
[X] the claims, Nos. NONE
[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/11589

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-23, 25-28	YES
	Claims	24	NO
Inventive Step (IS)	Claims	21-23, 25-27	YES
	Claims	1-20, 24, 28	NO
Industrial Applicability (IA)	Claims	1-28	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claim 24 lacks novelty under PCT Article 33(2) as being anticipated by Zurek et al.
Claims 1-5 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Dolphin.
Combs et al discloses a device and process for generating and measuring the shape of an acoustic reflectance curve of an ear, that further describes the use of a portable hand-held enclosure; a power supply connected to the signal processor; a signal processor having a program for producing auditory tests; a tympanometry interface operatively connected to the signal processor; an otoreflectance interface operatively connected to the signal processor; and an OAE simulator interface connected to the signal processor for testing the integrity of an OAE system.
Combs et al, however fails to disclose the use of a display device; and a plurality of electrodes for collecting data from the patient.
Dolphin discloses an audiometric apparatus and screening method that further discloses the use of a display device; and a plurality of electrodes for collecting data from the patient.
Since both Combs et al and Dolphin disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a display and electrodes, as per the teachings of Dolphin, since it would allow the processor to further determine the level of hearing of the a patient through the added data.

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Shennib.
Shennib discloses the use of a headset hearing tester that further discloses the use of an infrared interface connected to the signal processor for communicating between the signal processor and the external device.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Dolphin to include the use of an infrared interface, as per the teachings of Shennib, since it would permit the hearing test to be performed at a distance from the testing device.
(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII **Sheet 10**

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Claims 7-13 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Zurek et al.
Zurek et al discloses a means for testing the adequacy of human hearing that further discloses the use of a memory subsystem connected to the signal processor; a memory mapped input/output device connected to the memory subsystem and to the signal processor; and the signal processor performs a time domain sum averaged over time for obtaining OAE signal detection using a frame overlap method.
Since Combs et al, Dolphin, Shennib and Zurek et al disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Combs et al, Dolphin and Shennib to include the use of memory, as per the teachings of Zurek et al, in order to provide a means for accurately testing hearing.

Claims 14-17 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al and Zurek et al in view of Christiansen.
Combs et al discloses the use of connecting the probe to a hand-held device; generating an auditory signal in the device; detecting auditory signals generated in the ear; and converting the analog signals to digital signals.
Zurek et al discloses the use of sizing a new frame buffer for two primary tones and frequencies and a number od samples of tone produced by the ear; passing the data to a discrete Fourier transform to calculate the frequency specific magnitude and phase constant of the signal; comparing the magnitude and phase to a table to detect whether to reject the data; saving a copy of the frame data; sliding the date frame by a predetermined amount; collecting the data over a predetermined number of frames and averaging the data.
Christiansen discloses the use of storing the incoming data in a new frame buffer; converting the data to frequency domain and displaying the data to the user in the device in real-time.
It would have been obvious to one of ordinary skill in the art to modify the devices and methods of Combs et al and Zurek et al to include the memory and calculations of Christiansen, since it would provide a means of accurately determining the hearing levels of the patient.

Claim 18 lacks an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Zurek et al.
Combs et al discloses the use of a hand-held enclosure; a signal processor; and a display.
Zurek et al discloses the use of a memory module and a computer program.
It would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a memory module and a program, as per the teachings of Zurek et al since it would provide a means of testing one's hearing.

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Christiansen.
Christiansen discloses the use of a keyboard for accessing the computer program.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Zurek et al to include the use of a keyboard, as per the teachings of Christiansen, since it would provide access to the computer during the hearing test.

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over Christiansen in view of Combs et al.
Christiansen discloses the use of a signal processor; the processor having an OAE simulator program; the processor generating simulated tones in response to tones generated by the ear probe and the ear probe interface is connected to the processor.
Combs et al discloses the use of a hand-held enclosure.
It would have been obvious to one of ordinary skill in the art to modify the device of Christiansen to include the use of a hand-held enclosure, as per the teachings of Combs et al, since it would provide a means for easily carrying the hearing tester.

Claims 21-23 and 25-27 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the use of the formula contained in claims 21 and 25.

-------------------- NEW CITATIONS --------------------
NONE

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: LIONEL L. LUCCHESI
POLSTER, LEIDER, WOODRUFF & LUCCHESI, L.C.
763 SOUTH NEW BALLAS ROAD
ST. LOUIS, MISSOURI 63141

FILE COPY 416

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Form PCT/IPEA/416(July 1992) DO NOT MAIL

Date of Mailing
(day/month/year)

Applicant's or agent's file reference
7518

IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/US00/11389	28 APRIL 2000	29 APRIL 1999

Applicant
CAUSEVIC, ELVIR

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Facsimile No.
(703) 305-3230

ROBERT L. NASSER
PRIMARY EXAMINER

Authorized officer AND Telephone No.
BRIAN SZMAL (703) 308-0858

PATENT COOPERATION TREATY

FILE COPY 409

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Form PCT/IPEA/409 (cover sheet) (July 1998) FILE COPY - DO NOT MAIL

Applicant's or agent's file reference 7518	**FOR FURTHER ACTION** See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/11389	International filing date *(day/month/year)* 28 APRIL 2000	Priority date *(day/month/year)* 29 APRIL 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/00 and US Cl.: 600/559		
Applicant CAUSEVIC, ELVIR		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of _____ sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report
   II ☐ Priority
   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
   IV ☐ Lack of unity of invention
   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   VI ☐ Certain documents cited
   VII ☐ Certain defects in the international application
   VIII ☐ Certain observations on the international application

Date of submission of the demand 29 NOVEMBER 2000	Date of completion of this report 05 JULY 2001
Facsimile No. (703) 305-3230	Authorized officer AND Telephone No. BRIAN SZMAL (703) 308-0858

ROBERT L. NASSER
PRIMARY EXAMINER

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
Form PCT/IPEA/409 (Box I) (July 1998)
FILE COPY - DO NOT MAIL

International application No.
PCT/US00/11389

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the claims:
pages 16-20, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the drawing:
pages 1-5, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language ____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE
[X] the claims, Nos. NONE
[X] the drawings, ~~sheets/fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
Form PCT/IPEA/409 (Box V) (July 1998)
FILE COPY - DO NOT MAIL

International application No.
PCT/US00/11389

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-23, 25-28	YES
	Claims	24	NO
Inventive Step (IS)	Claims	21-23, 25-27	YES
	Claims	1-20, 24, 28	NO
Industrial Applicability (IA)	Claims	1-28	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claim 24 lacks novelty under PCT Article 33(2) as being anticipated by Zurek et al.
Claims 1-5 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Dolphin.
Combs et al discloses a device and process for generating and measuring the shape of an acoustic reflectance curve of an ear, that further describes the use of a portable hand-held enclosure; a power supply connected to the signal processor; a signal processor having a program for producing auditory tests; a tympanometry interface operatively connected to the signal processor; an otoreflectance interface operatively connected to the signal processor; and an OAE simulator interface connected to the signal processor for testing the integrity of an OAE system.
Combs et al, however fails to disclose the use of a display device; and a plurality of electrodes for collecting data from the patient.
Dolphin discloses an audiometric apparatus and screening method that further discloses the use of a display device; and a plurality of electrodes for collecting data from the patient.
Since both Combs et al and Dolphin disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a display and electrodes, as per the teachings of Dolphin, since it would allow the processor to further determine the level of hearing of the a patient through the added data.

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Shennib.
Shennib discloses the use of a headset hearing tester that further discloses the use of an infrared interface connected to the signal processor for communicating between the signal processor and the external device.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Dolphin to include the use of an infrared interface, as per the teachings of Shennib, since it would permit the hearing test to be performed at a distance from the testing device.
(Continued on Supplemental Sheet.)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Form PCT/IPEA/409 (Supplemental Box) (July 1998)

FILE COPY - DO NOT MAIL

International application No.

PCT/US00/11389

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Claims 7-13 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Zurek et al.
Zurek et al discloses a means for testing the adequacy of human hearing that further discloses the use of a memory subsystem connected to the signal processor; a memory mapped input/output device connected to the memory subsystem and to the signal processor; and the signal processor performs a time domain sum averaged over time for obtaining OAE signal detection using a frame overlap method.
Since Combs et al, Dolphin, Shennib and Zurek et al disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Combs et al, Dolphin and Shennib to include the use of memory, as per the teachings of Zurek et al, in order to provide a means for accurately testing hearing.

Claims 14-17 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al and Zurek et al in view of Christiansen.
Combs et al discloses the use of connecting the probe to a hand-held device; generating an auditory signal in the device; detecting auditory signals generated in the ear; and converting the analog signals to digital signals.
Zurek et al discloses the use of sizing a new frame buffer for two primary tones and frequencies and a number od samples of tone produced by the ear; passing the data to a discrete Fourier transform to calculate the frequency specific magnitude and phase constant of the signal; comparing the magnitude and phase to a table to detect whether to reject the data; saving a copy of the frame data; sliding the date frame by a predetermined amount; collecting the data over a predetermined number of frames and averaging the data.
Christiansen discloses the use of storing the incoming data in a new frame buffer; converting the data to frequency domain and displaying the data to the user in the device in real-time.
It would have been obvious to one of ordinary skill in the art to modify the devices and methods of Combs et al and Zurek et al to include the memory and calculations of Christiansen, since it would provide a means of accurately determining the hearing levels of the patient.

Claim 18 lacks an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Zurek et al.
Combs et al discloses the use of a hand-held enclosure; a signal processor; and a display.
Zurek et al discloses the use of a memory module and a computer program.
It would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a memory module and a program, as per the teachings of Zurek et al since it would provide a means of testing one's hearing.

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Christiansen.
Christiansen discloses the use of a keyboard for accessing the computer program.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Zurek et al to include the use of a keyboard, as per the teachings of Christiansen, since it would provide access to the computer during the hearing test.

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over Christiansen in view of Combs et al.
Christiansen discloses the use of a signal processor; the processor having an OAE simulator program; the processor generating simulated tones in response to tones generated by the ear probe and the ear probe interface is connected to the processor.
Combs et al discloses the use of a hand-held enclosure.
It would have been obvious to one of ordinary skill in the art to modify the device of Christiansen to include the use of a hand-held enclosure, as per the teachings of Combs et al, since it would provide a means for easily carrying the hearing tester.

Claims 21-23 and 25-27 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the use of the formula contained in claims 21 and 25.

------------------ NEW CITATIONS ------------------
NONE

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: LIONEL L. LUCCHESI
POLSTER, LEIDER, WOODRUFF & LUCCHESI, L.C.
763 SOUTH NEW BALLAS ROAD
ST. LOUIS, MISSOURI 63141

ENTERED 4/9/01

POLSTER, LIEDER, WOODRUFF & LUCCHESI
APR 06 2001
RECEIVED

PCT

WRITTEN OPINION

(PCT Rule 66)

	Date of Mailing (day/month/year) 03 APR 2001
Applicant's or agent's file reference 7518	REPLY DUE within TWO months from the above date of mailing

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US00/11389	28 APRIL 2000	29 APRIL 1999

International Patent Classification (IPC) or both national classification and IPC
IPC(7): A61B 5/00 and US Cl.: 600/559

Applicant
CAUSEVIC, ELVIR

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

   - I [X] Basis of the opinion
   - II [ ] Priority
   - III [ ] Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

   When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

   How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

   Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 *bis*. For an informal communication with the examiner, see Rule 66.6.

   If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 29 AUGUST 2001

Name and mailing address of the IPEA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	BRIAN SZMAL
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0858

WRITTEN OPINION

International application No.

PCT/US00/11389

I. Basis of the opinion

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:

pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the claims:

pages 16-20, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the drawings:

pages 1-5, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

[X] the sequence listing part of the description:

pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language ______ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*

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WRITTEN OPINION

International application No.
PCT/US00/11389

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-23, 25-28	YES
	Claims	24	NO
Inventive Step (IS)	Claims	21-23, 25-27	YES
	Claims	1-20, 28	NO
Industrial Applicability (IA)	Claims	1-28	YES
	Claims	NONE	NO

2. citations and explanations

Claim 24 lacks novelty under PCT Article 33(2) as being anticipated by Zurek et al.
Claims 1-5 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Dolphin.
Combs et al discloses a device and process for generating and measuring the shape of an acoustic reflectance curve of an ear, that further describes the use of a portable hand-held enclosure; a power supply connected to the signal processor; a signal processor having a program for producing auditory tests; a tympanometry interface operatively connected to the signal processor; an otoreflectance interface operatively connected to the signal processor; and an OAE simulator interface connected to the signal processor for testing the integrity of an OAE system.
Combs et al, however fails to disclose the use of a display device; and a plurality of electrodes for collecting data from the patient.
Dolphin discloses an audiometric apparatus and screening method that further discloses the use of a display device; and a plurality of electrodes for collecting data from the patient.
Since both Combs et al and Dolphin disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a display and electrodes, as per the teachings of Dolphin, since it would allow the processor to further determine the level of hearing of the a patient through the added data.

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Shennib.
Shennib discloses the use of a headset hearing tester that further discloses the use of an infrared interface connected to the signal processor for communicating between the signal processor and the external device.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Dolphin to include the use of an infrared interface, as per the teachings of Shennib, since it would permit the hearing test to be performed at a distance from the testing device.
(Continued on Supplemental Sheet.)

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

TIME LIMIT:
The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

Claims 7-13 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Zurek et al.
Zurek et al discloses a means for testing the adequacy of human hearing that further discloses the use of a memory subsystem connected to the signal processor; a memory mapped input/output device connected to the memory subsystem and to the signal processor; and the signal processor performs a time domain sum averaged over time for obtaining OAE signal detection using a frame overlap method.
Since Combs et al, Dolphin, Shennib and Zurek et al disclose means for testing hearing, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Combs et al, Dolphin and Shennib to include the use of memory, as per the teachings of Zurek et al, in order to provide a means for accurately testing hearing.

Claims 14-17 lack an inventive step under PCT Article 33(3) as being obvious over Combs et al and Zurek et al in view of Christiansen.
Combs et al discloses the use of connecting the probe to a hand-held device; generating an auditory signal in the device; detecting auditory signals generated in the ear; and converting the analog signals to digital signals.
Zurek et al discloses the use of sizing a new frame buffer for two primary tones and frequencies and a number od samples of tone produced by the ear; passing the data to a discrete Fourier transform to calculate the frequency specific magnitude and phase constant of the signal; comparing the magnitude and phase to a table to detect whether to reject the data; saving a copy of the frame data; sliding the date frame by a predetermined amount; collecting the data over a predetermined number of frames and averaging the data.
Christiansen discloses the use of storing the incoming data in a new frame buffer; converting the data to frequency domain and displaying the data to the user in the device in real-time.
It would have been obvious to one of ordinary skill in the art to modify the devices and methods of Combs et al and Zurek et al to include the memory and calculations of Christiansen, since it would provide a means of accurately determining the hearing levels of the patient.

Claim 18 lacks an inventive step under PCT Article 33(3) as being obvious over Combs et al in view of Zurek et al.
Combs et al discloses the use of a hand-held enclosure; a signal processor; and a display.
Zurek et al discloses the use of a memory module and a computer program.
It would have been obvious to one of ordinary skill in the art to modify the device of Combs et al to include the use of a memory module and a program, as per the teachings of Zurek et al since it would provide a means of testing one's hearing.

Claims 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Christiansen.
Christiansen discloses the use of a keyboard for accessing the computer program.
It would have been obvious to one of ordinary skill in the art to modify the devices of Combs et al and Zurek et al to include the use of a keyboard, as per the teachings of Christiansen, since it would provide access to the computer during the hearing test.

Claim 28 lacks an inventive step under PCT Article 33(3) as being obvious over Christiansen in view of Combs et al.
Christiansen discloses the use of a signal processor; the processor having an OAE simulator program; the processor generating simulated tones in response to tones generated by the ear probe and the ear probe interface is connected to the processor.
Combs et al discloses the use of a hand-held enclosure.
It would have been obvious to one of ordinary skill in the art to modify the device of Christiansen to include the use of a hand-held enclosure, as per the teachings of Combs et al, since it would provide a means for easily carrying the hearing tester.

Claims 21-23 and 25-27 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the use of the formula contained in claims 21 and 25.

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Supplemental Box
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Continuation of: Boxes I - VIII

Sheet 11

-------------------- NEW CITATIONS --------------------
NONE

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PCT

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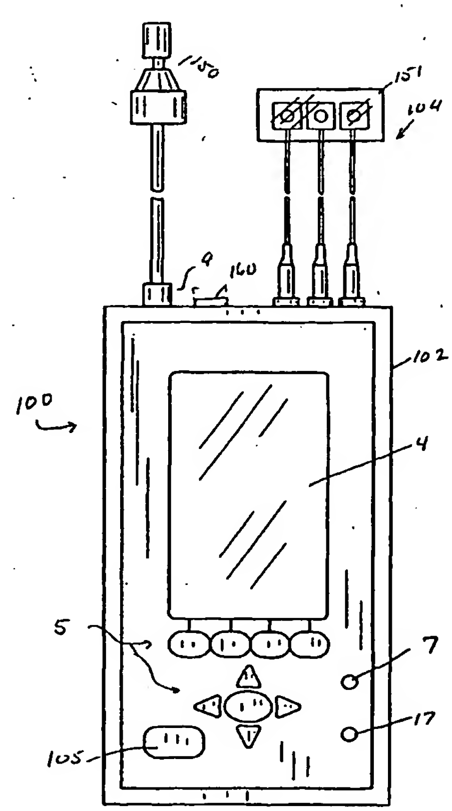
(54) Title: HANDHELD AUDIOMETRIC DEVICE AND METHOD OF TESTING HEARING

(57) Abstract

Handheld apparatus (100), and method for comprehensive hearing testing with pass/refer results applicable for large scale neonatal screening, adult screening, or full hearing diagnostic is disclosed. The apparatus (100) contains a signal processor (1), integral ear probe (150), and remote ear, and scalp probes (104) all packaged as a single handheld battery operated device (100). The apparatus (100) preferably performs a battery of tests, either independently or combined: oto-acoustic measurements utilizing a novel digital signal processing method for evoked oto-acoustic signal processing, auditory brain stem response test, tympanometry, and oto-reflectance. Algorithms for automatic test sequence, and pass/refer indication for the tests are provided.



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HANDHELD AUDIOMETRIC DEVICE AND METHOD OF TESTING HEARING

Technical Field

This invention relates to the field of auditory measurement devices and associated screening methods. In particular, the invention relates to a hand-held auditory measurement device, which has features beneficial to all neonatal screening programs. While the invention is described with particular emphasis to its auditory screening application, those skilled in the art will recognize the wider applicability of the inventive principles disclosed hereinafter.

Background Art

Universal neonatal auditory screening programs have expanded greatly because of improved auditory measurement capability, improved rehabilitation strategies, increased awareness of the dramatic benefits of early intervention for hearing impaired babies, and changes in governmental policies. Current neonatal auditory screening approaches, however, do not account adequately for the many different types and degrees of auditory abnormalities that are encountered with present screening approaches. Because of this, individual screening tests based on a single measurement can be influenced negatively by interaction among various independent auditory abnormalities. Current screening approaches have not considered adequately the entire screening program including (i) physical characteristics of the measurement device i.e., portability, physical size and ease of use, (ii) operational characteristics of the device i.e., battery life, amount of record storage, required operating training, etc. and/or (iii) program logistics i.e., retesting mechanisms, referral mechanisms, record processing, patient tracking, report writing, and other practical aspects. These factors can interact negatively to increase the total cost of an auditory screening program, including the primary economic cost of screening, testing, the secondary economic cost of additional testing, and non-economic costs such as parental anxiety incurred when provided with incorrect information.

These costs, both actual and human, can be reduced by reducing the cost per test, reducing the false positive rate, and resolving false positive screening results at the bedside prior to hospital discharge. The cost per screening can be reduced with a dedicated device optimized for screening in any location and enhanced to allow effective operation by minimally trained personnel. The performance characteristic of the device of our invention includes reduced measurement time, the ability to operate and configure without an external computer, the ability to integrate and interpret all test results, the ability to store large number of test results, long battery life, and bi-directional wireless transfer of data to and from external devices.

We have found false positive results can be reduced in two ways. First, the initial screening test performance can be improved with enhanced signal processing, more efficient test parameters, and by combining different types of tests. Second, false positive rates also can be reduced by providing a mechanism for resolving an initial screening test failure at the bedside at the time of the initial screening. This capability is provided through the availability of an automated screening auditory brainstem response (ABR) test capability provided by the same device. Secondly, operational processes of a screening program can be improved through the use of several onboard computer based expert systems. These computer based expert systems provide improved automatic interpretation of single test results, automatic interpretation of multiple test results, and improved referral processes through the matching of local referral sources with various test outcomes, such as a referral to a specific type of follow-up, whether it be a pediatrician, audiologist, otolaryngologist, or a nurse. The device disclosed hereinafter integrates in a single, hand-held device, a single stimulus transducer, a single processor and a single software application for otoacoustic emission (OAE), ABR testing, tympanometry and otoreflectance, as well as OAE simulator.

An auditory abnormality is not a single, clearly defined entity with a single cause, a single referral source and a single intervention strategy. The peripheral auditory system has three separate divisions, the external ear, the middle ear, and the sensorineural portion consisting of the inner ear or cochlea,

and the eight cranial nerve. Abnormalities can and do exist independently in all three divisions and these individual abnormalities require different intervention and treatment. Prior art physical and operational characteristics of devices and their influences on program logistics can interact negatively to increase the total cost of an auditory screening program. The primary economic cost is the cost of each screening test though this is not the only economic cost. A screening test failure is called a "refer" and usually is resolved with an expensive full diagnostic test scheduled several weeks after hospital discharge, resulting in significant economic cost. A substantial portion of these costs is unnecessary if the screening false positive rate is high. Non economic costs include parental anxiety for false positive screening results, unfavorable professional perception of program effectiveness for programs with high false positive rates and even inappropriate professional intervention because of misleading screening results.

The intervention of multiple measurements into a single hand-held instrument allows for very important new functionality not available with existing neonatal auditory screening devices. This functionality includes (1) detection of common external and middle ear abnormalities; (2) the detection of less common sensorineural hearing loss associated with outer hair cell abnormalities, and (3) the detection of even less common sensorineural hearing loss associated with inner hair cell or auditory nerve abnormality. Moreover, the device disclosed hereinafter has the potential to improve the accuracy and reliability of OAE measurements, to allow for optimal interpretation of both the OAE and ABR results, and to improve the referral process.

Attempts have been made in the past to provide the capabilities provided by the present invention. In particular, U.S. Patent Nos. 5,601,091 ('091) and 5,916,174 ('174) disclose audio screening apparatus which purport to provide a hand-held portable screening device. However, the screening device disclosed in those patents is used in conjunction with a conventional computer, and requires a docking station for full applicational use. In no way does the disclosure of either patent provide a hand-held device that can be used independently of any other computer. That is to say, the invention disclosed hereinafter provides a device of significantly reduced size i.e., hand-held, which

is capable of providing OAE and ABR testing, as well as tympanometry otoreflectance, and OAE simulator. It can be operated in a stand-alone mode, independently of any other computer connection, if desired. The device includes a patient database, with names, and full graphic display capability. The device also preferably is provided with a wireless infrared and an RS 232 connection port to provide output directly to printers or to a larger database where such is required.

The '174 and '091 patents also operate on a linear averaging method to remove background noise. While such method works well for its intended purposes, use of a linear averaging method is time consuming. Consequently, we developed a frame overlap method for rejecting noise and improving signal reliability in a device which measures, in the embodiment illustrated, 7 ¼" x 3 ¾" x 1 ½".

<u>Summary of Invention</u>

One of the objects of this invention is to provide a reduced size hand-held device for auditory screening which provides OAE, ABR, tympanometry, otoreflectance and OAE simulator operation.

Another object of this invention is to provide an audio screening device, which is hand-held and operates in a fully stand-alone mode, operating independently of any other computer connection.

Another object of this invention is to provide a hand-held device that provides a patient database on the device.

Another objection of this invention is to provide a hand-held audio screening apparatus that provides for full graphic display on the device itself.

Another object of this invention is to provide a device that increases noise rejection and reduces processing time through the use of frame overlapping techniques.

A further object of this invention is to provide a device with ABR testing that automates electrode impedance checking prior to test.

Another object of this invention is to provide a device which is low in cost, and which can be adapted to provide a wide ranging of auditory screening applications.

In accordance with this invention, generally stated, an effective auditory screening method and device are provided. The integration of an OAE screening device and ABR screening device into a single, hand-held instrument enables a user to detect less common sensorineural hearing loss associated with outer hair cell abnormalities and the detection of less common sensor hearing loss associated with inner hair cell abnormalities. In the preferred embodiment, the device includes a portable hand-held enclosure containing a digital signal processor. The processor has a computer program associated with it, capable of conducting both otoacoustic emission test procedures and auditory brainstem response test procedures for a test subject. A display device is mounted to the enclosure, and displays patient information, test setup procedure, and test results including graphing of test results. The enclosure includes a connection point for a probe, the connection point being operatively connected to the signal processor. The device also includes an onboard power supply, making the device completely self contained.

A method of testing OAE response in a test subject is provided which utilize a unique method of noise reduction to provide acceptable data even in high level ambient noise conditions of the test subject's environment.

Brief Description Of The Drawings

In the drawings, Figure 1 is a top plan view of one illustrative embodiment of audio screen device of the present invention.

Figure 2 is a view in end elevation;

Figure 3 is a view in end elevation of the end opposite to that shown in Figure 2

Figure 4 is a block diagrammatic view of the device shown in Figure 1;

Figure 5 and 6 are block diagrammatic views of the algorithm employed with the device of Figure 1 in connection with ABR testing;

Figure 7 is a diagrammatic view of frame sliding implemented by the algorithm of Figure 4; and

Figure 8 is a block diagrammatic view of the algorithm implemented with respect to OAE testing to improve the signal to noise ratio employed with the device of Figure 1.

Best Mode for Carrying out the Invention

The following detailed description illustrates the invention by way of example and not by way of limitation. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what we presently believe is the best mode for carrying out the invention. It will nevertheless be understood that no limitation in the scope of the invention is thereby intended, and that alterations and further modifications of the illustrative devices is contemplated, including but not limited to further applications of the principles of the invention illustrated herein as would normally occur to one skilled in the art to which this invention relates.

Referring now to Figures 1 - 3, reference numeral 100 illustrates one illustrative embodiment of the audio screening device of the present invention. The screening device 100 includes an enclosure 102, which in the preferred embodiment, and for purposes of illustration and not for limitation, measures 7 ¼" long by 3 ¾" wide by 1 ½" deep. It is important to note that the device 100 can be carried by the user without compromise, and truly represents a portable hand-held device having full functionality as described below. The device 100 includes a keyboard 5, a LCD display 4 an LED pass/refer indicator 7 and an LED AC charging indicator 17. Again, by way of illustration and not by limitation, it should be noted that the screen 4 measures, in the preferred embodiment, approximately, 2" by 3 3/8". The measurement is not necessarily important, except to show that the LCD display is fully functional for a user, and the unit can operate independently of any other computer system. In the embodiment illustrated, the enclosure 102 also houses an infrared port 18, and a compatible RS-232 port 18a, a probe connection 9 for an ear probe 150, and an interface 103 for a plurality of electrodes 104. The electrodes 104 are shown attached to a conventional carrier 151.

Ear probe 150 is conventional and is not described in detail. Suitable probes are commercially available from Etymotic Research, Part No. ER-10C, for example.

A novel feature of this invention is the provision of an OAE simulator ear probe interface 160. The simulator function permits a user to test the integrity of the entire OAE test system, by providing active feedback and simulation of a test subject's ear.

Referring now to Figure 2, a block diagram view of the device 100 is shown and described. The device 100 contains OAE, ABR and OAE simulator capabilities in a single, hand-held package. Preferably, the system shown in Figure 2 is manufactured on a single printed circuit board, with mixed signal design for both analog and digital operation. The device preferably is low powered, and generally operates at 3.3 volts, except for the LCD 4 and some low power portions of the analog circuitry employed with the device 100.

A digital signal processor 1 is the control for the device 100. In the preferred embodiment illustrated, the processor 1 is a Motorola chip DSP 56303. All signal processing functions described hereinafter are performed by the processor 1, as well as the control of all input and output functions of the device 100. In addition, the graphic functions, user interface, patient data storage functions and other device functionality are controlled by the processor 1. In conventional design logic, the digital signal processor 1 is used for signal processing, and a separate micro controller is used for device control. We have been able to eliminate the separate microprocessor, resulting in substantial savings in space, cost and power consumption.

A memory subsystem 2 is operatively connected to the processor 1. The memory subsystem 2 includes a random access memory 2a for storing intermediate results and holding temporary variables, and a flash memory 2b for storing non-volatile, electrically programmable variables, patient data and configuration information. In the embodiment illustrated, the flash memory 2b is substantially oversized, enable the device 100 to accommodate as many as 300 full patient records, as well as multiple configurations files.

A memory mapped input/output device 3 is operatively connected to the memory subsystem 2 and to the digital signal processor 1. The memory mapped input/output 3 in turn is operatively connected to the LCD display 4, the keyboard 5, the pass/referral LED indicator 7 and a real time clock 6.

The LCD display 4 is the largest non-custom LCD available. While custom LCD displays can be obtained, they add prohibitive cost to the product. The LCD display 4 provides the user with 128 x 256 pixels of graphics. That display is sufficient to present full waveforms of audiometric tests conducted by the device 100. The keyboard 5 preferably is a membrane switch keyboard, which incorporates only the minimum keys necessary for operation of the device 100. All keys are programmable, except for the on/off key 105.

A real time clock 6 is operatively connected to the processor 1 through the memory mapped device 3. The clock 6 enables the processor 1 to provide a time stamp for each patient and test performed, as well as providing time signals for internal operation of the device 100.

The LED pass/refer diode 7 is used to convey test results to non-trained users, namely a nurse as opposed to an audiologist or otolaryngologist. Use of the LED 7 avoids confusion or misinterpretation of the LCD graphics display 4, and allows use of the device 100 in low light areas, where the LCD display 4 may be difficult to interpret.

The plurality of analog to digital/digital to analog coder/decoders 8 (codecs 8) is operatively connected to the signal processor 1. As will be appreciated by those skilled in the art, the codecs 8 are special integrated circuit chips that perform analog to digital and digital to analog conversion. The codecs 8 are operatively connected to the signal processor 1 along a dedicated serial link indicated by the reference numeral 107. The codecs 8 in turn are operatively associated with a plurality of input/output devices, which provide the functionality of the device 100 under control of the processor 1.

An otoacoustic emission interface 9 is operatively connected to the signal processor 1 through the associated codecs 8. The interface 9 preferably is a low noise, differential analog circuit with high common mode noise rejection. The interface 9 is intended to drive two sound transducers inserted in the ear canal which produce a variety of signals, from pure tones at various frequencies to chirps, clicks, sinc waveforms etc. The otoacoustic emission interface 9 can present tones at all standard audiometric frequencies and sound pressure levels. The device employed with the interface 9 includes a microphone, also inserted

in the ear canal, which collects signals coming back from the ear, and provides sufficient linear amplification to present the signals to the codecs 8. In various embodiments of this invention, the interface 9 also can be used for otoreflectance measurements for assessing some middle ear conditions.

The ABR interface 80 consists of a plurality of analog signal processing chips, not shown individually, which filter and amplify the signals connected from the scalp of a subject via electrode wires 104. In this mode of operation, the ear is presented with a repeated auditory stimulus, which causes firing of the eighth nerve, and the associated nerve pass into the brainstem. As those firings occur, electrical potentials are generated all the way to the scalp, and there they are detected by the electrodes 104. An additional function of the interface 9 is to provide automated impedance check of the placement of electrodes. Once the electrodes are in place, a small current is injected through the electrodes into the scalp of the subject, and the impedance between electrodes is measured. Impedance can be varied by placement of the electrodes. Once the impedance is within the predetermined range for operation, ABR signal connection can begin. It is important to note that impedance checking can be accomplished without unplugging the electrodes. That is to say checking is automatic. As latter described in greater detail, the measured ABR response is based on the detection of a peak in the waveform in a point approximately up to 15 milliseconds after a sound click, depending upon gestational age or patient age. The actual latency of this peak is then compared to the latency of this peak in normal hearing neonates or adults.

The otoacoustic emission simulator interface 11 is used to check the integrity of the OAE system. It includes a transducer or speaker and a microphone. The microphone collects the signals presented by the OAE probe, presents them to the codecs 8 and processor 1 for signal processing, and then the speaker presents the corresponding tone at the correct frequency and amplitude back to the original OAE probe thus providing an active, calibrated test cavity.

Our invention optionally may include a tympanometry interface 11a in place of the interface 11. The tympanometry interface 11a comprises an

electronic output channel to drive a miniature pump, not shown, which can produce pressure or a vacuum in the ear canal of a test subject. A corresponding pressure sensor is used to measure this pressure, and the signal from the pressure sensor is fed into an analog input of the codecs 8.. The signal can be used as an independent feature, and the device will show full graphics output on the LCD 4 in real time. In the alternative, this test may be used in combination with the OAE or ABR test to compensate for middle ear conditions.

A mode configuration system 12, a reset watchdog system 13, a crystal clock 14, a power supply 15 and a battery charger 16 all are also positioned within the enclosure 102 and operatively connected to the processor 1. While each of these blocks is required for operation of the device 102, they are standard in nature and are not described in detail.

The processor 1 has an input output channel 18, which are preferably an infrared connection and an isolated RS-232 interface. The device 100 can communicate with any infrared compatible or RS-232 compatible personal computer, printer, or other digital device for data transmission. Data transmission may include patient information, configuration data for the signal processor 1, or software program updates.

A buzzer 19 also is provided. The buzzer 19 provides an audio feedback to the user for keyboard actions and audio indication for error conditions.

A serial port 20 also is operative connected to the processor 1. The serial port 20 is utilized to provide direct programming of the processor 1 from a personal computer, for example, and is intended for use only for initial software download and major software program upgrades of the processor 1.

A distortion product otoacoustic emission (DPOAE) is a tone generated by a normal ear in response to the application of two external tones. When two tones, f_1 and f_2 are applied to an ear, the normal non-linear outer hair cells generate a third tone f_{dp}, which is called a distortion product. F_{dp} then propagates from the outer hair cells back to the ear canal where it is emitted. The level of the DPOAE can be used as a measure of outer hair cell function. If the outer hair cell system is absent or otherwise not functioning properly, the

non-linearity will be absent or reduced and the f_{dp} will either not be generated or generated at a lower than expected level.

The measured DPOAE is highly dependent upon the specific tones that invoke it. The frequencies of f_1 and f_2, and their respective levels in the ear canal, L1 and L2 must be controlled precisely. Under known signal conditions, the largest distortion product is generated at a very specific frequency ($f_{dp} = 2 f_1 - f_2$), and level L_{dp}. Comparison of the level of L_{dp} with known values from individuals with normal outer hair cell systems forms the basis of the decision of whether the patient either passed the screening (pass/refer LED 7) or requires a referral for a more complete diagnostic testing.

Signals other than pure tones can be presented to the ear, which will also evoke a response from the ear, such as clicks, chirps, etc. DPOAE is used to as an example, the other stimuli would be processed the same way.

The processor 1 utilizes a unique method of detecting signals for the OAE test. While the method is a time domain sum and average operation, the key concept is to reuse data from adjacent frames to average with the current frame. This method is described for the purpose of this specification as "sliding". The limit to the size of the overlap is the auto correlation of original data. The method works on the assumption that the data within the overlap frames is different, and that the noise is uncorrelated. It is key to keep the frame size an integer number (one or more) of the original data cycles.

The important difference between the method of the present invention and linear averaging is that the overlapping number M (sum operation) equals (frame number divided by frame size minus 1 times frames size divided by frame data cycle length plus 1 which is larger than the received data frame number in by a factor by which the previous frame is slid. Therefore, the expected performance of this method is better than standard linear averaging. In this method, the frame size divided by frame data cycle length must be an integer. The method is shown diagrammatically in Figure 5.

The processor 1 algorithm is implemented and explained in with reference to Figure 4. As there shown, the processor 1 sends an output through the digital analog converter portion of the codecs 8 through the OAE interface 9

to the ear probe utilized in conjunction with the device 100. The ear probe includes a microphone which returns signals through the interface 9 and the codecs 8 to a new frame buffer 111 in the processor 1. The size of the new frame buffer 111 is calculated to be an integer number of samples of the two primary tones at frequencies f1 and f2, and also, an integer number of samples of the otoacoustic tone produced by the ear at f_{dp}. This is a critical step to assure quality of subsequent signaling processing, by avoiding windowing techniques, which can introduce substantial artifacts. Tables of numbers for each standard frequency employed in the device 1 and for other frequencies in use or intended use in the device 1 are available, and are programmed into the algorithm once the user selects the test frequencies. Should a combination of frequencies be required for which no common integer number can be found to fit in a practical size frame, the frame size is adjusted to f_{dp} and the frame is windowed prior to Fourier Transformation, but this method is used only in extreme cases since in normal operation, the required frequencies are available.

The data from the single frame is passed to a point Discrete Fourier Transform 112 (DFT) block which calculates the signal's magnitude and phase content, but only at frequencies of interest, including f_1, f_2, f_{dp} to determine a noise floor. Windowing is induced prior to DFT to reduce edge effects, although windowing induces energy at other bands. The block 112 is used only for temporary calculations, and the windowed data is not reused again. The output of block 112 is the magnitude and phase of primary signals at f_1 and f_2 and the noise floor figure of time at f_{dp} . The output of block 112 forms an input to frame rejection block 113 and to an on-line calibration calculation block 114.

With the information on the magnitudes at various frequencies, a noise calculation algorithm is employed at and around f_{dp} to determine the noise floor. The magnitude of the noise floor and frequency content are used against a set of predetermined conditions i.e. a comparison against an empirically derived table contained in the processor 1, to determine the outcome of the frame. That outcome has three distinct possibilities. First, if the noise magnitude and frame content exceed a multi-threshold condition at measured frequency bands, the new frame is rejected. Second, if the noise magnitudes fall between a set of

reject thresholds and a set of accept thresholds, the data in the frame is disregarded, but the noise information is kept to update the noise level average. Third, if the noise magnitudes are below the accept thresholds, the frame is kept and passed on for further processing and the noise magnitudes are averaged together with the noise average of the previous frame. This information is used to update thresholds, such that the system adapts to environmental conditions.

When the information about magnitudes of primary tones at f_1 and f_2, and the noise floor information at and around f_{dp}, an online calibration of the level of magnitudes takes place. Several actions occur in the calibration block 114. First, if the noise floor is large when no primary tones are present, the frequency of the primaries is adjusted within predetermined limits. A new f_{dp} is calculated, and the noise content of frequency bins at and around f_{dp} is checked again. This process is repeated until a stable, low noise floor is established. No primary tones are played through the speaker through this process. Once the primaries are presented, they are stepped up to the full output amplitude, as programmed by the user and calibrated in the ear by increasing the output of the codecs 8. No data collection from the ear has taken place yet. At this time, if the level is not reached in a user predetermined time, and at the rate of increase of the primaries, the test is aborted due to lack of fit or the low quality of fit of the probe in the ear canal. Once the proper fit is achieved, and testing begins, data collection takes place. During the entire process of data collection, the levels of tones at f_1 and f_2 are checked to ensure that they remain within predetermined limits throughout the test. If they exceed those limits, the output is adjusted up or down to compensate until a maximum compensation limit is reached, at which time, the test is aborted and the user is notified. Also, the magnitude at and around f_{dp} is continuously monitored to assure low noise floor, and if necessary, the frequency of the primary tones are adjusted on-line within predetermined limits to avoid the high external noise region. The change in frequencies of the primaries is minimal, and within the specified tolerances of the device 100, and have been shown not to affect the magnitude of the tone within the ear at fdp.

The block 115 is a store/copy buffer. As a frame is collected in new frame buffer 111, a copy of it is saved for processing of the subsequent frames. The buffer 115 receives frame data from new frame buffer 111. The store and copy frame buffer 115 has a variable depth, depending the number of frames averaged together. Buffer 115 provides an output to a block 116 and a block 117. The block 116 operates with the stored previous frames, which are slid by a predetermined amount and the empty spaces padded with zeros for subsequent processing in the averaging old and new frame block 117.

In block 117, the frames are averaged together to reduce the uncorrelated noise present. Theoretically, the noise is reduced by a factor of one over the square root of the number of averaged frames. The frames are averaged in a linear fashion, sample by sample and a new frame is created at the end of the averaging operation. The advantage of this method is that the data is essentially correlated against a slid copy of itself, slid far enough away to avoid averaging the same information content. This provides either a substantial reduction in uncorrelated noise energy for the same amount of sampling time or a substantial reduction in sampling time to obtain the equivalent noise reduction when compared to standard linear averaging.

The minimum limit to the sliding of the data, and to the reuse of old data frame is the autocorrelation function of the data in the frame, which can be predetermined or calculated on-line. This method is equivalent to taking much smaller frames and averaging them together. However, for the purposes of the subsequent Fourier Transformations and filtering taking place, the frame size is required to be large (i.e., 960 samples at 48 kilohertz sampling rate), to obtain several full cycles of each of the tones at f1, f2 and fdp. The problem with taking a large number of very small frames is that the Fourier Transforms or other signal processing methods require several cycles of data for proper operation. The method of the present invention outperforms standard linear averaging of large frames because of the reduction in time as well as providing proper operation of the Fourier Transforms.

The block 118 obtains the averaged data from the block 117, and collects it in a buffer that is used for subsequent processing and signal statistics.

The output of the block 118 is digitally filtered in the block 119. The filter 119 removes any remaining high or low frequency components not required for final data presentation.

The averaged and filtered data is converted to frequency domain, in the embodiment illustrated, by using a discrete Fourier Transform in the block 120, and the data then is ready for presentation in block 121. As will be appreciated by those skilled in the art, other signal processing methods are available to convert data, and those other methods are compatible with the device 100.

As indicated above, the device 100 enables the LCD 4 to present information to a user graphically in real time on the device itself, complemented with textual and numeric information about the quality of the fit, amplitudes, frequency, noise floors and other related information.

Operation of the device for ABR testing is shown in Figure 3. In ABR testing, the magnitude of the fifth peak is the one that is of primary interest, and the device 100 determines the magnitude of the fifth peak by counting zero crossings, after substantial filtering and digital pre-processing. As shown in Figure 3, the system proceeds to count zero crossings and stores an index of an array element upon determination of a zero crossing. If additional zero crossings are required, the procedure is repeated until the fifth peak is determined. Upon detection, the single waveform is isolated, and the waveform peak is correlated to find the maximum correlation sinusoid. Thereafter, the device 1 determines the time of occurrence of the fifth peak and that value is check against empirical data to obtain proper correlation.

Numerous variations, within the scope of the appended claims, will be apparent to those skilled in the art in light of the foregoing description and accompanying drawings. For example, the design of the enclosure may vary in other embodiments of the invention. Likewise, LCD display 4 may be replaced with other display devices. As indicated in the specification, we use a discrete Fourier Transform to obtain data for display. Other signal processing methods are compatible with the broader aspects of the invention. These variations are merely illustrative.

Claims:

1. An auditory screening device, comprising:

a portable hand-held enclosure;

a signal processor housed by said enclosure, said processor having a computer program operated on command by a user, said program producing auditory tests selected from the group comprising otoacoustic emission (OAE) test procedures, auditory brainstem response (ABR) test procedures, tympanometry, otoreflectance and combinations thereof for a test subject;

a display device mounted to said enclosure, said display device being operatively connected to said signal processor, said display device displaying the results of the selected test in real time;

a connection point on said enclosure for a probe, the connection point being operatively connected to said signal processor; and

a power supply for operating the signal processor.

2. The screening device of claim 1 further including a plurality of electrodes for collecting data from a patient, said electrodes being operatively connected to said signal processor.

3. The device of claim 2 further including a tympanometry interface operatively connected to said signal processor for recording middle ear pressure on a test subject and adjusting minor middle ear conditions during OAE and ABR testing.

4. The device of claim 3 further including an otoreflectance interface operatively connected to said signal processor for recording assessing middle ear conditions on a test subject.

5. The device of claim 4 further including an OAE simulator interface operatively connected to said signal processor for testing the integrity of an OAE system.

6. The device of claim 5 further including an infrared interface operatively connected to said signal processor for permitting communication between said signal processor and an external device.

7. The device of claim 6 further including a memory subsystem operatively connected to said signal processor.

8. The device of claim 7 further including a memory mapped input/output device operatively connected to said memory subsystem and to said signal processor, said display being operatively connected to said signal processor through said memory mapped device.

9. The device of claim 8 further including a keyboard, said keyboard being operatively connected to said signal processor through said memory mapped device.

10. The device of claim 9 wherein said power supply is rechargeable.

11. The device of claim 1 wherein said signal processor performs a time domain sum and average over time for obtaining OAE signal detection using a frame overlap method.

12. The device of claim 11 wherein said memory subsystem includes provisions for patient data.

13. The device of claim 12 wherein the ABR test signal is determined by digital signal processing and counting zero crossings of correlated internally generated sinusoids.

14. A method of conducting an OAE audio test, comprising the steps of inserting a probe in a patient's ear, the probe including a speaker and a microphone;

connecting the probe to a hand-held device;

generating an auditory signal in the hand-held device;

detecting auditory signals generated in the ear via the microphone;

converting the analog signals to digital signals;

storing the incoming data in a new frame buffer;

sizing the new frame buffer so that it is an integer number of samples of two primary tones and frequencies f_1 and f_2 and also an integer number of samples of the tone produced by the ear defined by the frequency f_{dp};

passing the data from a single frame to a discrete Fourier transform process to calculate the frequency specific magnitude and phase content of the signal;

comparing the magnitude and phase to a table to detect whether to reject the data, discard the data but update a noise table, or accept the data;

saving a copy of the frame data;

sliding the date frame by a predetermined amount;

collecting the data over a predetermined number of frames;

averaging the data;

converting the data to frequency domain; and

displaying the data to a user in a hand-held device in real time.

15. The method of claim 14 further including the step of saving the data internally of the device.

16. The method of claim 15 further including the step of sending to the user an indication of the subject passing or failing the test.

17. The method of claim 16 further including the step of transferring the data from the device to a second external unit.

18 An auditory screening device comprising;

a hand-held enclosure;

a signal processor within said enclosure;

a memory module within said enclosure operatively connected to said signal processor;

a display screen mounted to said enclosure, said display screen being operatively connected to said signal processor;

a computer program at least partial contained in said signal processor, said computer program being accessible by a user to perform an otoacoustic emission test and an auditory brainstem response test for a test subject, said memory module maintaining a plurality of test subject records for display on said display screen;

19. The screening device of claim 18 further including a keyboard for accessing said computer program.

20. The device of claim 19 wherein the OAE information is recorded by frames, and information from a preceding frame is used in connection with information of a succeeding frame to reduce the signal to noise level in the received signals.

21. The device of claim 20 wherein the amount of information employed with a succeeding frame is obtained from the formula:

$$M = \left(\frac{f_n}{f_s - 1}\right) \times \left(\frac{f_s}{f_{dcl} + 1}\right)$$

where M equals overlap number, f_n equals frame number, f_s equals frame size and f_{dcl} equals frame data cycle length.

22. The device of claim 21 wherein said computer program further includes tympanometry test procedures conducted independently or in conjunction with OAE and ABR tests. .

23. The device of claim 22 wherein the computer program determines data information for the brainstem response test by counting zero crossing of a sinusoid.

24. A method of conducting an OAE otoacoustic test in which reduced signal to noise ratio is obtained by:

receiving OAE signal information in frames;

overlapping information from a proceeding frame for use in connection with information from a succeeding frame;

making a determination to accept the data, reject the data, but update noise average or discard the data based upon predefined parameters.

25. The method of claim 24 wherein an overlap is determined from the formula:

$$M = \left(\frac{f_n}{f_s - 1}\right) \times \left(\frac{f_s}{f_{dcl} + 1}\right)$$

where M equals overlap number, f_n equals frame number f_s equals frame size, and f_{dcl} equals frame data cycle length.

26. The method of claim 25 further including the step of conducting an auditory brainstem response (ABR) test for a test subject.

27. The method of claim 26 wherein data for the ABR test is obtained by counting zero crossings of an internally generated, correlated sinusoid.

28. An auditory screening device comprising:
a portable hand-held enclosure;
a signal processor housed by said enclosure;
said processor having an OAE simulator program at least partially contained in said processor; said processor generating simulated f_{dp} tones in response to tones generated by an ear probe; and
an ear probe interface operatively connected to said processor.

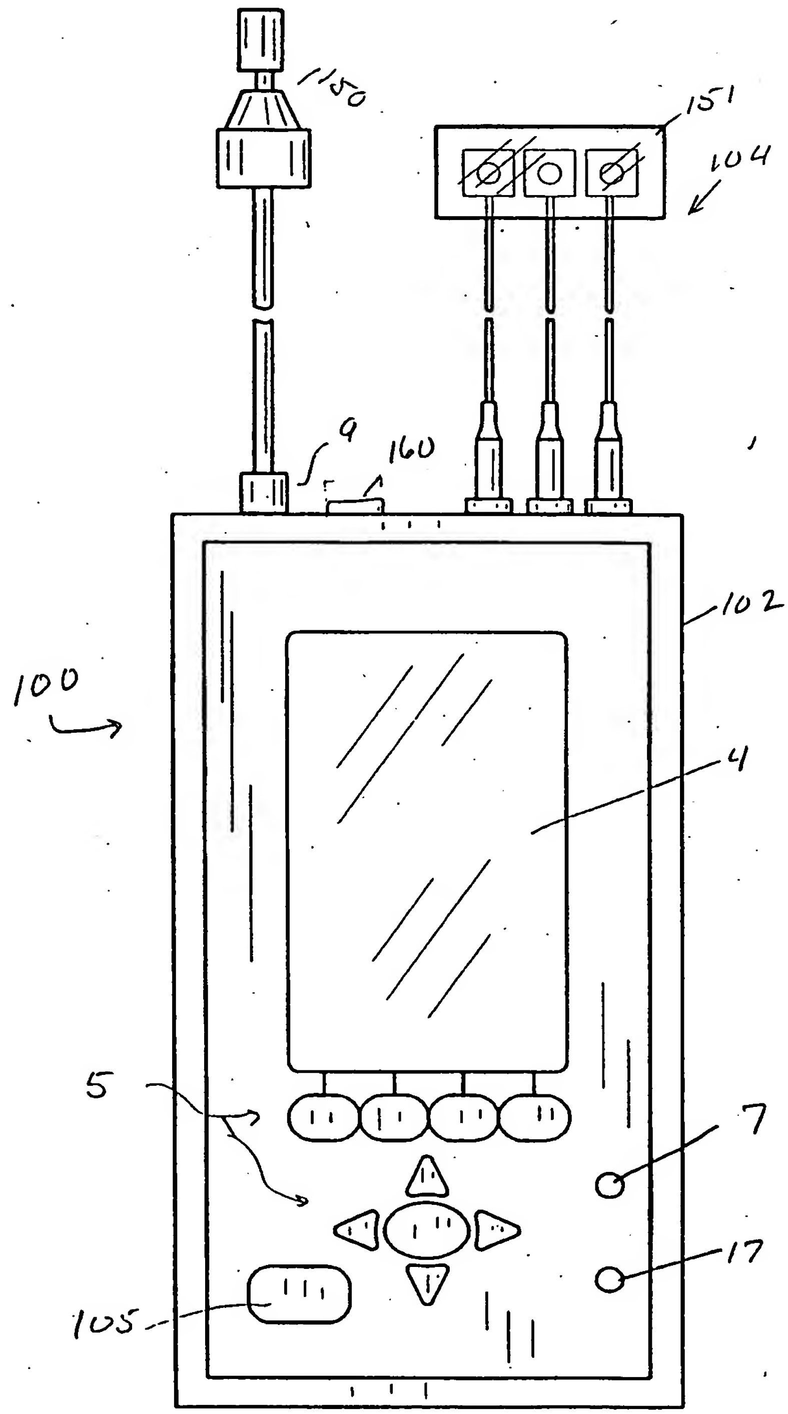

FIG. 1

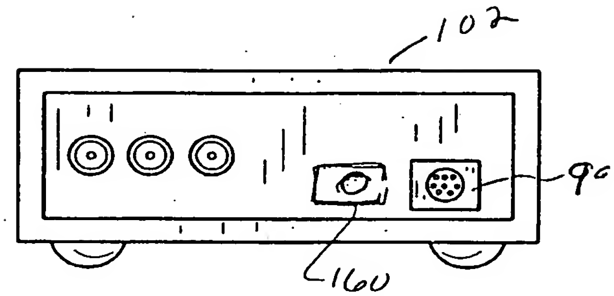

FIG. 2

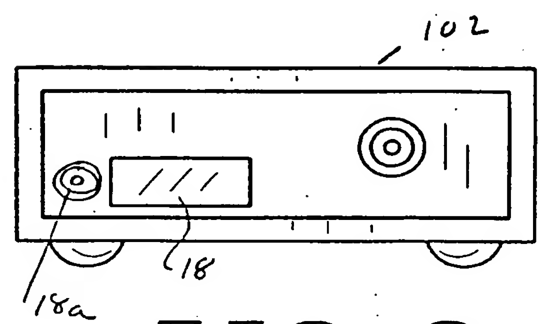

FIG. 3

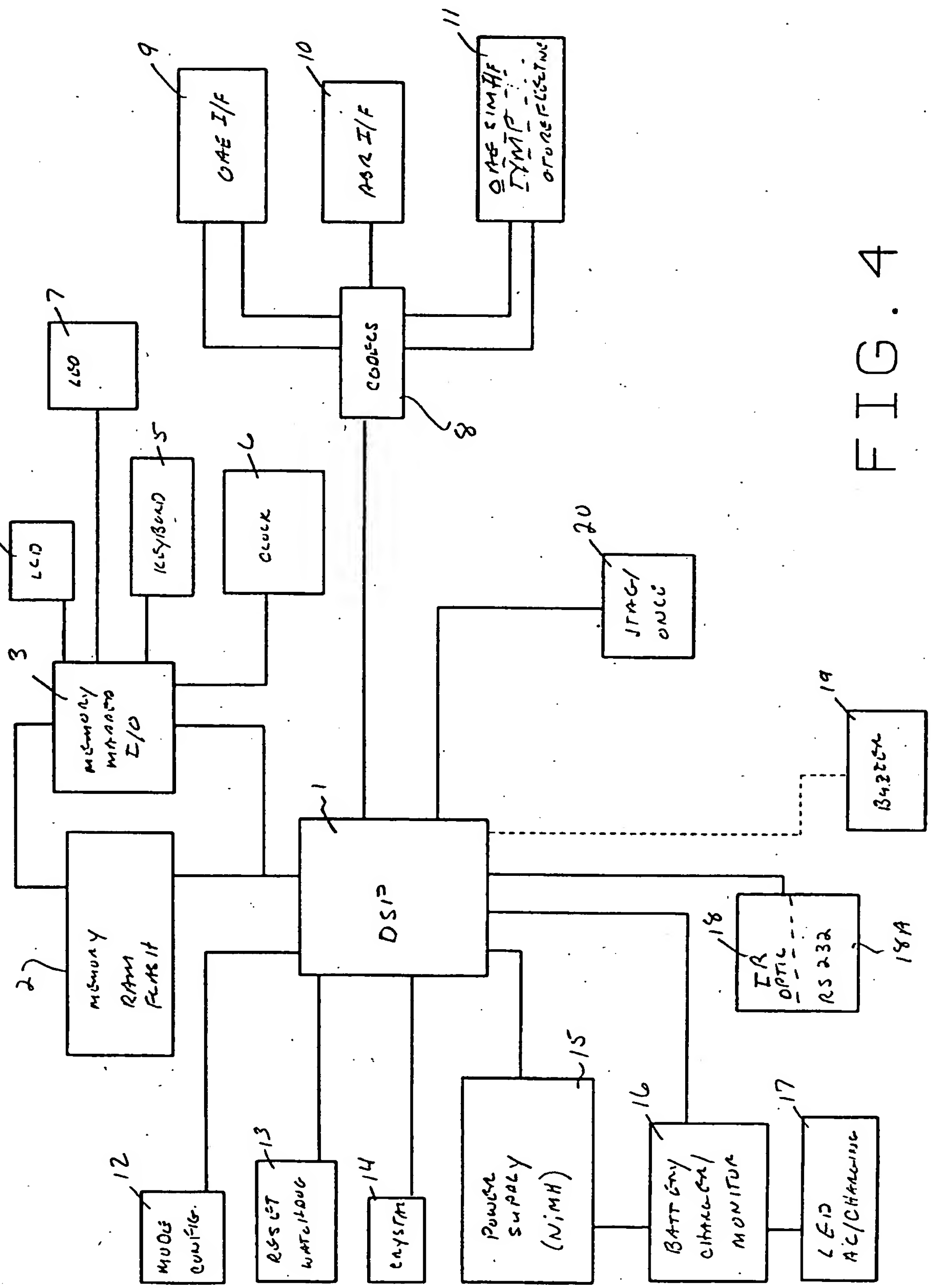
OAE I/F
ABR I/F
CODECS
LCD
KEYBOARD
CLOCK
MEMORY MAPPED I/O
MEMORY RAM FLASH
DSP
JTAG/ONCE
BUZZER
IR OPTIC
RS 232
MODE CONFIG.
RESET WATCHDOG
CRYSTAL
POWER SUPPLY (NiMH)
BATTERY CHARGER/MONITOR
LED AC/CHARGING
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
18A
19
20

FIG. 4

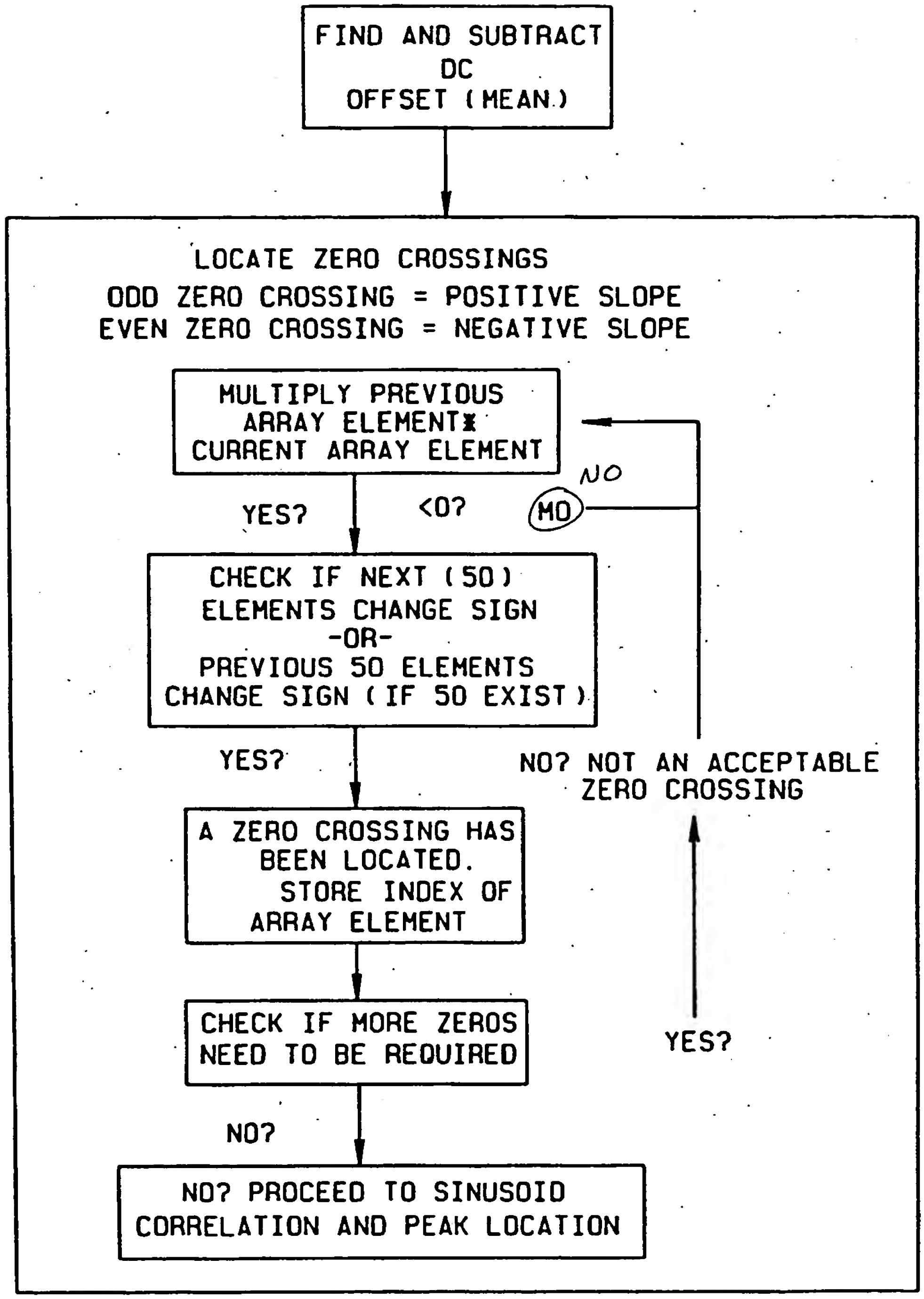
FIND AND SUBTRACT DC OFFSET (MEAN)
LOCATE ZERO CROSSINGS
ODD ZERO CROSSING = POSITIVE SLOPE
EVEN ZERO CROSSING = NEGATIVE SLOPE
MULTIPLY PREVIOUS ARRAY ELEMENT* CURRENT ARRAY ELEMENT
YES?
<0?
NO
MO
CHECK IF NEXT (50) ELEMENTS CHANGE SIGN -OR- PREVIOUS 50 ELEMENTS CHANGE SIGN (IF 50 EXIST)
YES?
NO? NOT AN ACCEPTABLE ZERO CROSSING
A ZERO CROSSING HAS BEEN LOCATED. STORE INDEX OF ARRAY ELEMENT
CHECK IF MORE ZEROS NEED TO BE REQUIRED
YES?
NO?
NO? PROCEED TO SINUSOID CORRELATION AND PEAK LOCATION

FIG. 5

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SINUSOID CORRELATION AND PEAK DETECTION

ISOLATE SINGLE WAVEFORM PEAK BETWEEN CONSECUTIVE ZEROS

↓

GENERATE (100) HALF-SINUSOIDS. EACH SINUSOID VARIES IN FREQUENCY BY (0.000025) CYCLES/SAMPLE

↓

CORRELATE WAVEFORM PEAK WITH EACH SINUSOID AND FIND MAXIMUM CORRELATION SINUSOID.

↓

LOCATE TIME OF PEAK BY MULTIPLYING 1/SAMPLING FREQUENCY TIMES INDEX OF LEFT SIDE ZERO OF INITIAL WAVEFORM PLUS THE LENGTH OF ONE QUARTER OF THE SINUSOID WITH MAXIMUM.

FIG. 6

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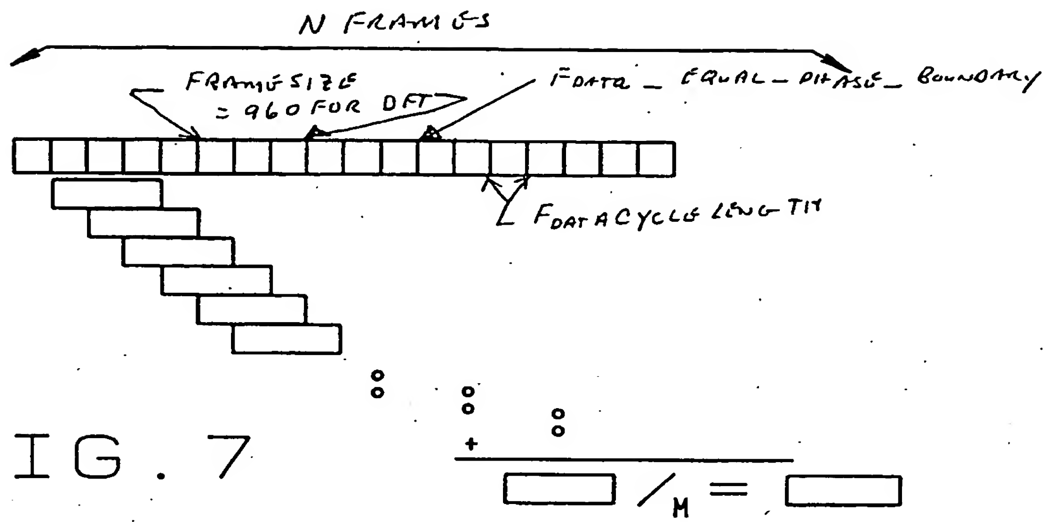
N FRAMES
FRAMESIZE = 960 FOR DFT
FDATA _ EQUAL _ PHASE _ BOUNDARY
FDATA CYCLE LENGTH
+
/M =

FIG. 7

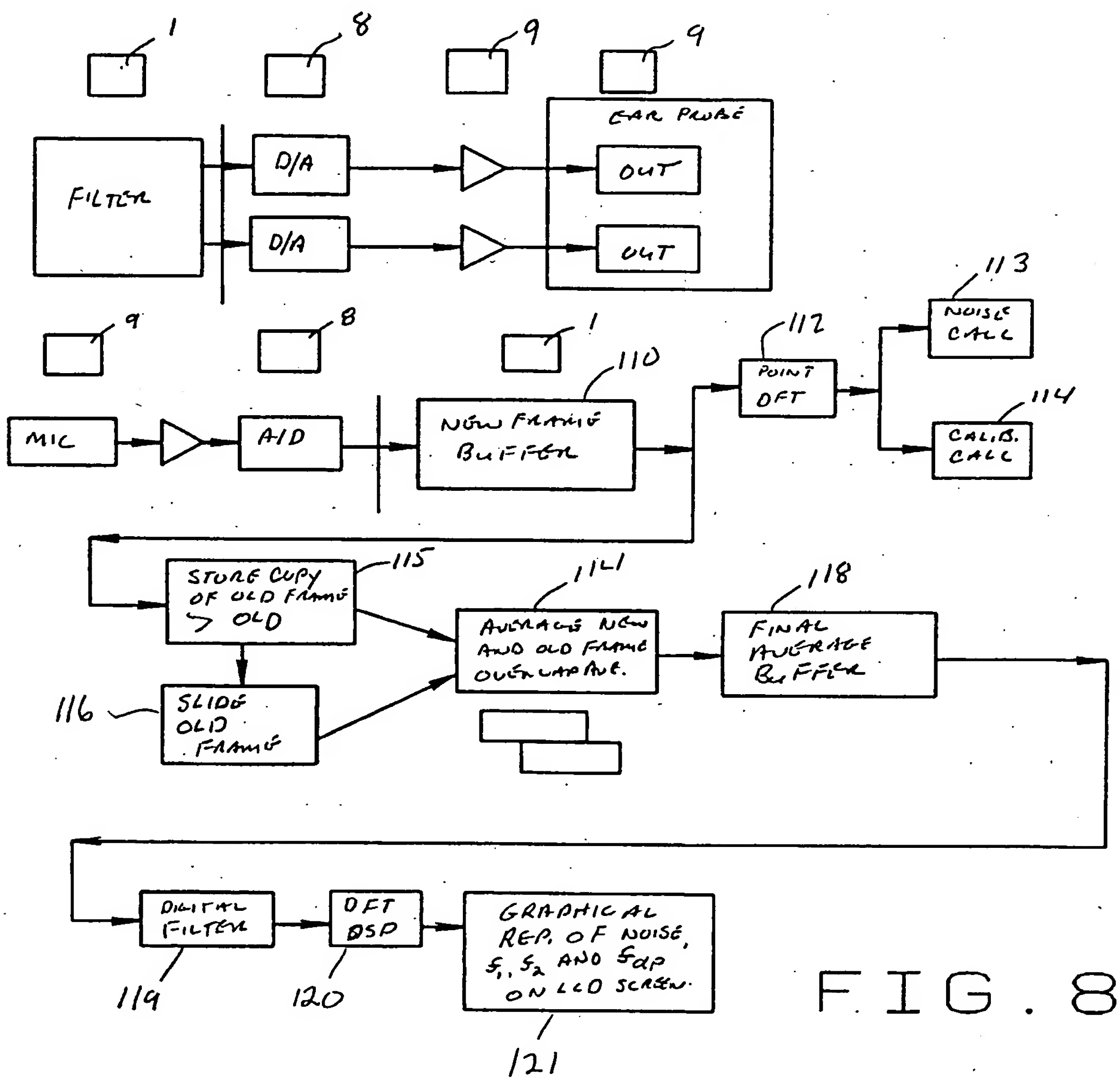
1
8
9
9
FILTER
D/A
D/A
EAR PROBE
OUT
OUT
9
8
1
113
NOISE CALC
112
POINT DFT
110
MIC
A/D
NEW FRAME BUFFER
114
CALIB. CALC
STORE COPY OF OLD FRAME > OLD
115
114
AVERAGE NEW AND OLD FRAME OVERLAP AVE.
118
FINAL AVERAGE BUFFER
116
SLIDE OLD FRAME
DIGITAL FILTER
DFT DSP
GRAPHICAL REP. OF NOISE, S_1, S_2 AND S_{dp} ON LCD SCREEN.
119
120
121

FIG. 8

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/11389

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/559
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/28, 300, 559

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST
Search Terms: ear, test, hearing, otoacoustic, OAE, ABR, hand-held, computer, display

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,267,571 A (ZUREK et al.) 07 December 1993, whole document.	24 ----------------- 7, 8, 11-18, 20-23
Y	US 5,601,091 A (DOLPHIN) 11 February 1997, whole document.	1, 2, 25-27
Y	US 5,738,633 A (CHRISTIANSEN) 14 April 1998, whole ducument.	1, 9, 10, 14-17, 19, 28
Y	US 5,197,332 A (SHENNIB) 30 March 1993, whole document.	6
Y	US 5,868,682 A (COMBS et al.) 09 February 1999, whole document.	1, 3-5, 14-18, 28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 JUNE 2000	28 JUL 2000

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	BRIAN SZMAL
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